UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT[1]

[1] Plaintiffs' Motion for Partial Summary Judgment concerns the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"); specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC ("MSP"), as class representative of TPP Breach of Express Warranty Subclass B, TPP Breach of Implied Warranty Subclass D, TPP Fraud Subclass C, and TPP State Consumer Protection Laws Subclass A (collectively, the "TPP Classes"). (ECF 2343 at 1-2.) Accordingly, this brief is limited to the TPP Trial Claims, and is presented without waiver of any arguments with respect to any other claims asserted by any Plaintiff as to any Defendant in this multi-district litigation. Capitalized terms in this brief have the same meaning as in the TPP Trial Defendants' Omnibus Motion for Summary Judgment (ECF 2562-1) and Omnibus Statement of Material Facts Not in Dispute (ECF 2571).

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INTRODUCTION

In its recent Opinion on Liability Expert Reports under FRE 702 (ECF 2581) ("Rule 702 Opinion"), the Court held that Plaintiffs' central theory of their case—i.e., that Defendants' VCDs were "adulterated"—"is only for the fact-finder to reach." (ECF 2581 at 19.) Plaintiffs' Motion for Partial Summary Judgment (ECF 2569-1) ("Pls.' Br.") nonetheless asks the Court to invade the province of the jury and decide as a matter of law that: (1) Defendants' life-saving VCDs were adulterated because they contained trace amounts of NDMA or NDEA; and (2) the alleged presence of these purported impurities constituted breaches of express warranties under the laws of 20 states and deceptive or unfair conduct under the laws of 18 states. Plaintiffs' motion fundamentally misapprehends the nature of Rule 56, which is designed to resolve claims in their entirety rather than decide discrete issues that would not materially advance the litigation. Indeed, Plaintiffs do not even address notice, causation/reliance, or injury—other elements of Plaintiffs' claims—which they cannot satisfy for the reasons elaborated in Defendants' Motion for Summary Judgment. Even if the Court disagrees, Plaintiffs would still have the burden of proving these essential elements at trial. Plaintiffs' motion should be denied for this reason alone.

Plaintiffs' motion independently fails on the merits because Plaintiffs do not come close to establishing the elements they address in their motion. Instead, they

highlight, at best, factual disputes that jurors should decide after both sides present their evidence at trial.

Express warranty. Plaintiffs seek to avoid any trial on whether Defendants made any express warranties and whether Defendants breached any such purported warranties on the ground that the Court declined to dismiss their claims at the pleading stage. But, as explained in Defendants' Omnibus Motion for Summary Judgment (ECF 2562-1) ("Defs.' Br.") and accompanying Omnibus Statement of Material Facts Not in Dispute (ECF 2571) ("Defs.' SUMF"), the evidence in the record from both of the class representatives forecloses Plaintiffs' express warranty claims because one assignor who testified in this case (SummaCare) affirmatively stated that Defendants made no express warranties to it, and the second (Emblem) was not aware of any purported warranties. Even if this evidence did not entitle Defendants to summary judgment on Plaintiffs' express warranty claims, it would more than suffice to defeat Plaintiffs' request for partial summary judgment.

Plaintiffs also argue that they are entitled to partial summary judgment on the question of breach, based primarily on the FDA's 2018 warning letter, which they claim specifically found that ZHP's API was adulterated. But a warning letter is an advisory statement, not a definitive finding by the FDA, which is presumably why the Court repeatedly recognized in its most recent Rule 702 Opinion that the question of adulteration is for the fact-finder to resolve. This is all the more true in light of

the FDA's numerous clarifying statements underscoring the unforeseeable nature of the potential for nitrosamine formation in the VCDs and Plaintiffs' experts' own concessions regarding the applicable standards, state of knowledge, and available testing before 2018. Plaintiffs' other theories of breach fail in light of the substantial evidence that Defendants' products were in fact what they purported to be (therapeutically equivalent and bioequivalent valsartan) and complied with CGMPs and all applicable compendial and regulatory standards. Accordingly, if Defendants had expressly warranted that their VCDs were not adulterated or complied with specific regulatory standards (and they did not), it is up to the jury to decide whether Defendants' medications lived up to those supposed promises.

Consumer protection. Plaintiffs also ask the Court to hold, as a matter of law, that Defendants' conduct was "deceptive" or "unfair" under 18 consumer protection statutes for the same reasons Plaintiffs claim Defendants breached supposed express warranties. However, the applicable states' consumer protection statutes apply vastly different and varying standards, and Plaintiffs have made no attempt to demonstrate their satisfaction of ***any*** state's consumer protection standard as a matter of law. Moreover, as elaborated in Defendants' own Motion for Summary Judgment, the record precludes Plaintiffs from establishing that Defendants engaged in deceptive or unfair conduct under any standard. To the extent the Court disagrees, Plaintiffs' arguments with regard to deception and unfairness—which are similar to

those they make in connection with their express warranty claims—at most raise questions of fact that should be decided by the jury.

ARGUMENT

Summary judgment is proper under Rule 56(c) only where the movant shows that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (citation omitted). In reviewing a motion for summary judgment, a court "may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)).

"Although the language of Rule 56 permits a party to move for summary judgment on all or part of a claim, 'the validity of a motion seeking judgment of some non-liability element of a claim that would not resolve at least one entire claim is questionable in federal courts.'" *Evans v. Nat'l Auto Div., L.L.C.*, No. 15-8714, 2016 WL 4770033, at *4 (D.N.J. Sept. 12, 2016) (quoting *Avaya, Inc. v. Telecom Labs, Inc.*, No. 06-2490, 2009 WL 2928929, at *2 (D.N.J. Sept. 9, 2009)). This is particularly true where the plaintiff is seeking partial summary judgment on an element that is "so interlocked with the other elements of the case" that "the issue

cannot be resolved alone." *Evans*, 2016 WL 4770033, at *4 (denying partial summary judgment on whether defendants received prior, express written consent under the Telephone Consumer Protection Act because plaintiff would still have to establish multiple other elements).

The Court should deny Plaintiffs' motion under these principles because: (1) it would not resolve Plaintiffs' express warranty or consumer protection claims in their entirety; and (2) numerous genuine issues of material fact preclude judgment as a matter of law.

I. PLAINTIFFS ARE NOT ENTITLED TO PARTIAL SUMMARY JUDGMENT ON THEIR CLAIMS FOR BREACH OF EXPRESS WARRANTY.

A. Plaintiffs' Request For Partial Summary Judgment Is Improper Because It Ignores Multiple Liability Elements.

As elaborated in Defendants' Motion for Summary Judgment, Plaintiffs' express warranty claims fail because they do not have any evidence capable of establishing multiple independent elements of their claims: (1) that any Defendant made an express warranty; (2) that any Defendant breached a purported warranty; (3) that Plaintiffs and the Express Warranty Subclass B members relied on such a warranty; (4) that Plaintiffs provided Defendants with reasonable pre-suit notice of any purported breach; and (5) that Plaintiffs and the subclass members were injured as a result of any breach of warranty. (*See* Defs.' Br. at 16-18, 24-28.) Plaintiffs' inability to establish any of these independent elements entitles ***Defendants*** to

summary judgment and renders Plaintiffs' competing motion moot.

But even if Plaintiffs could establish a material dispute of fact as to any of these independent elements, their motion would still be improper because it addresses, at most, just two elements of their express warranty claims: the existence of an express warranty and breach of that warranty. *See Feuerstack v. Weiner*, No. 12-04253, 2014 WL 3619675, at *2 (D.N.J. July 22, 2014) ("[F]or [p]laintiff to obtain summary judgment on his claims, he must show that, on ***all*** the essential elements of the case on which he bears the burden of proof at trial, no reasonable jury could find for [d]efendant.") (emphasis added). Plaintiffs ignore the other elements of their express warranty claims, including pre-suit notice, reliance and injury, effectively conceding that disposition of their motion would not establish liability and would fail to "materially advance the litigation in any way." *In re G-I Holdings Inc*., No. 02-3082, 2007 WL 1412294, at *4 (D.N.J. May 14, 2007).[2] For

[2] Plaintiffs' footnoted cases either support Defendants' point or are inapposite. For example, in *Hirst v. Elgin Metal Casket Co.*, the court noted in passing that it had previously "granted, on its own motion, a summary judgment to the effect that there had been a breach of warranty" based on a satisfaction of ***all*** of the elements required for liability by uncontroverted evidence. 438 F. Supp. 906, 906-07 (D. Mont. 1977) (cited in Pls.' Br. at 6 n.3). In *Promuto v. Waste Management, Inc.*, the "defendants[] d[id] not challenge the fact that the express warranties were breached. Rather, they argue[d] that a genuine issue of fact exists with respect to plaintiffs' . . . reliance on the warranties"—which the court rejected based on undisputed evidence that "the express warranties [were] bargained-for terms of the [agreement]." 44 F. Supp. 2d 628, 643 (S.D.N.Y. 1999) (citation omitted) (cited in Pls.' Br. at 6 n.3). And in *Enpro Systems, Ltd. v. Namasco Corp.*, the parties did not dispute that the testing report at

this reason alone, Plaintiffs are not entitled to summary judgment on their claims for breach of express warranty.

B. Plaintiffs Have Not Established That Each Defendant Made Express Warranties.

Even as to the elements of their express warranty claims that Plaintiffs do address, their arguments fail. Plaintiffs rely on the Court's motion-to-dismiss ruling to argue that Defendants made express warranties that (1) "their valsartan API (in the case of ZHP) and finished-dose valsartan, or VCDs (in the case of ZHP, Teva and Torrent) were the FDA-approved and USP-compliant formulations of those products, as listed in the Orange Book" (Pls.' Br. at 2-3); and (2) "their product met all compendial requirements" (*id.* at 7). But the Court's ruling that Plaintiffs had sufficiently pled the existence of an express warranty is not a legitimate basis for granting Plaintiffs partial summary judgment as to either of their two theories.

First, the Court's prior ruling did not even address, much less endorse, Plaintiffs' theory that Defendants expressly warranted that the VCDs met compendial standards, complied with CGMPs and were not adulterated. Nor have Plaintiffs identified any statement by Defendants (on the product labeling, packaging or otherwise) suggesting, much less guaranteeing, that the medications satisfied these purported standards. *See Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-

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issue "makes some kind of express warranty." 382 F. Supp. 2d 874, 877, 888 n.48 (S.D. Tex. 2005) (cited in Pls.' Br. at 7 n.3).

1777, 2010 U.S. Dist. LEXIS 67109, at *37 (N.D. Tex. June 30, 2010) (granting defendant summary judgment on express warranty claim because "plaintiffs have not produced evidence showing that Bionics made an express affirmation or promise that the devices were within PMA specifications"); *see also Zutz v. Case Corp.*, 422 F.3d 764, 775-76 (8th Cir. 2005) (affirming grant of summary judgment because "[n]o evidence in the record indicates that Case expressly warranted the 5010 Drill, and no evidence indicates Case extended any representations regarding the 4010 Drill to the 5010 Drill") (footnote omitted).

Plaintiffs rely instead on general citations to the FDA's searchable database and unsubstantiated assertions that Defendants "affirmatively marketed" their products as "US grade," "FDA-approved," "the generic or therapeutic equivalent of DIOVAN®," and meeting "all compendial requirements"—statements found nowhere in Plaintiffs' Statements of Material Facts ("SUMFs") or the accompanying exhibits. (*See* Pls.' Br. at 7; ZHP SUMF ¶¶ 126-34, 145-54; Teva SUMF ¶¶ 37-40; Torrent SUMF ¶¶ 32, 36, 37, 57.) Plaintiffs' subjective gloss on as-yet-unidentified statements cannot suffice to withstand Defendants' own summary judgment motion, much less decide the question in Plaintiffs' favor.[3]

[3] Notably, the only case involving an adulteration-based theory of express warranty cited by Plaintiffs involved "[a]n attachment to each purchase order" expressly representing that the medication was "not adulterated . . . within the meaning of the Food, Drug, and Cosmetic Act" and was "in compliance with applicable regulations

Second, the Court's prior ruling also fails to justify partial summary judgment in favor of Plaintiffs on their theory that Defendants expressly warranted to Plaintiffs' assignors and the subclass members that the VCDs were the equivalent of branded valsartan in the Orange Book. Although the Court held that Plaintiffs had adequately alleged such a theory at the dismissal stage, it was required to "accept all factual allegations as true" and merely "afforded [Plaintiffs] an opportunity to offer evidence in support of their claims." (ECF 775 at 10 (citations omitted).) At this more advanced stage, the undisputed record does not support a grant of partial summary judgment in favor of Plaintiffs (to the contrary, it disproves Plaintiffs' allegations). *See Conopco, Inc. v. McCreadie*, 826 F. Supp. 855, 867 n.5 (D.N.J. 1993) ("It goes without saying, of course, that a statement in the course of denying a motion to dismiss based solely on the face of the complaint is not binding . . . ."); *see also Williams v. Meese*, 986 F.2d 1432 (table), 1993 WL 53539, at *3 (10th Cir. 1993) (factual allegations "are not sufficient to ward off a motion for summary judgment").

Most notably, SummaCare's representative has since testified that it had no "warranties in place" with the TPP Trial Defendants, while Emblem's representative

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thereunder." *Alra Lab'ys, Inc. v. Am. Cyanamid Co.*, No. 92 C 2252, 1996 WL 377070, at *1 (N.D. Ill. July 2, 1996) (cited in Pls.' Br. at 10). And even then, the court denied summary judgment because the question of adulteration was a "factual issue," *id.* at *4, the same conclusion the Court should reach here.

testified that it was not aware of any express warranties regarding valsartan. (Defs.' SUMF ¶¶ 84-85.) In addition, the Court previously excluded Plaintiffs' only expert evidence of an express warranty (Dr. Kaliopi Panagos's opinion that a generic drug listing and rating in the Orange Book supposedly constitutes a manufacturer's "warranty"), as exceeding her expertise (ECF 2261 at 94)—a ruling that the Court reiterated in its more recent Rule 702 Opinion (*see* ECF 2581 at 23). None of the materials highlighted in Plaintiffs' brief (e.g., the Drug Master File and Abbreviated New Drug Applications ("ANDAs") and agreements between ZHP and other TPP Trial Defendants) is to the contrary, as Plaintiffs have no evidence that any of the documents or communications they refer to were shared with, or intended to be shared with—much less constituted an affirmation or promise to—Plaintiffs' assignors and the subclass members. In short, the record makes clear that Plaintiffs cannot establish the existence of any express warranty, entitling ***Defendants*** to summary judgment on this cause of action.

But even if Plaintiffs could withstand Defendants' Motion for Summary Judgment, "whether a given statement constitutes an express warranty is normally a question of fact for the jury." *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 324 (D.N.J. 2014) (citation omitted); *Small v. Amgen, Inc.*, 2 F. Supp. 3d 1292, 1298 (M.D. Fla. 2014) (similar). That principle applies here in the event the Court denies Defendants' Motion for Summary Judgment, because what (if any) express

affirmations or promises are contained within the terms "valsartan" or "valsartan API" is, at a minimum, a disputed issue of fact. As evidenced by the parties' competing summary judgment papers, the parties dispute whether the terms by themselves imply that the products are FDA-approved and United States Pharmacopeia ("USP")-compliant formulations of those products, as listed in the Orange Book, and met all compendial requirements. (*Compare* Defs.' SUMF ¶¶ 88-94, *with* ZHP SUMF ¶ 145; Torrent SUMF ¶ 37; Teva SUMF ¶ 37.) And even if the Court were to find that there is no material dispute that the terms incorporated the Orange Book or USP standards, as Plaintiffs assert, there is a disputed issue of fact regarding what those standards required with respect to nitrosamine impurities in VCDs at the time in question. (*Compare* Defs.' SUMF ¶¶ 68, 72, 73, 75, 118, *with* ZHP SUMF ¶ 127; Torrent SUMF ¶ 37; Teva SUMF ¶ 37.) These questions require a jury's determination.

Plaintiffs' authorities are inapposite, as they involved specific written warranties or uncontested breaches. *See Hirst*, 438 F. Supp. at 906-07 (involving a "written warranty" that the casket met "the rigid specifications and quality control promised you" and uncontroverted evidence that the casket contained water); *Promuto*, 44 F. Supp. 2d at 643 ("defendants[] d[id] not challenge the fact that the express warranties were breached"); *Enpro Sys.*, 382 F. Supp. 2d at 877, 888 n.48 (parties did not dispute that the testing report at issue "certif[ied] that the contents of

this report are accurate and correct") (citation omitted). No comparable evidence exists here. For this reason, too, Plaintiffs are not entitled to summary judgment on their claims for breach of express warranty.

C. Plaintiffs Have Not Established That Each Defendant Breached Express Warranties.

As explained in Defendants' Motion for Summary Judgment, Plaintiffs cannot prove that Defendants breached any express warranty, even if one existed. The alleged presence of trace levels of NDMA or NDEA in the VCDs did not violate any purported warranty that these VCDs were "the same" or were generic versions of their reference listed drugs ("RLDs"). (Defs.' SUMF ¶ 89.) This is so because at the time the recalled VCDs were approved by the FDA, and continuing through the time of the recalls beginning in July 2018, the levels of any impurities in the VCDs at issue were within the specification limits approved by the FDA, and the VCDs remained pharmaceutically equivalent and bioequivalent to the RLDs. (*Id.* ¶¶ 68, 72-73, 86-94, 98-101.)[4]

Plaintiffs nevertheless argue that they are entitled to summary judgment on the question of breach because "[t]he FDA explicitly found that ZHP's API was adulterated in its November 29, 2018 Warning Letter." (Pls.' Br. at 9-10.) But, in its

[4] The Court's Rule 702 Opinion confirms that the expert opinions supporting these undisputed facts will be admitted, with certain exclusions and limitations not relevant here. Defendants have limited their use of these experts' opinions in the present opposition brief in accordance with the Court's rulings.

recent Rule 702 Opinion, the Court held that whether the VCDs were "adulterated" "is only for the fact-finder to reach," essentially recognizing that jurors should decide this fundamental question. (ECF 2581 at 19.) Moreover, warning letters "fail to satisfy" either condition for final agency action; "they neither mark the consummation of the agency's decisionmaking nor determine the [recipient's] legal rights or obligations." *Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 943-45 (D.C. Cir. 2012). Rather, they are "of a merely tentative or interlocutory nature" and therefore do not "determin[e] rights or obligations" "from which legal consequences will flow." *Id.* at 943-44 (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)); *see also, e.g.*, FDA, FDA Form 483 Frequently Asked Questions, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed Jan. 20, 2024) (warning letter "does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations"); FDA, Regulatory Procedures Manual § 4-1-1 at 4 (June 2022), https://www.fda.gov/media/71878/download (last accessed Jan. 20, 2024) ("A Warning Letter is informal and advisory.").

For these reasons, courts have repeatedly held that "a warning letter and a voluntary recall notice do not establish an applicable standard of care," let alone suffice to prove a breach of such a standard. *Gross v. Stryker Corp.*, 858 F. Supp. 2d

466, 497 (W.D. Pa. 2012); *see, e.g.*, *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 280, 282 (E.D.N.Y. 2009) (two warning letters issued by the FDA "mentioning defendants' violations of federal regulations" did not establish "the necessary connection" to the specific devices and defects at issue in the case); *see also, e.g.*, *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (similar); *Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 227 (W.D.N.Y. 2016) (finding a "plausible causal connection" to be "entirely lacking"); *Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203(JS)(WDW), 2014 WL 2863087, at *5 (E.D.N.Y. June 23, 2014) (similar).

Although Plaintiffs insist that the FDA's "finding alone is dispositive" (Pls.' Br. at 10), the cases they cite do not support their argument. For example, in *Alra Laboratories, Inc.*, 1996 WL 377070, the court ***denied*** summary judgment, reasoning that there was a "factual issue as to whether . . . GMP violations render[ed] the [medication] . . . adulterated" notwithstanding the FDA's findings and even though a prior jury had found the party "guilty of criminal charges involving adulteration." *Id.* at *4-5. And in *United States v. 286,161 Bottles*, the government filed a complaint for forfeiture in rem for dietary supplements it had seized based on the FDA's Form 483. Although the court granted the government's motion for judgment on the pleadings, it did not reference the FDA's Form 483 (much less assign it "dispositive" weight); rather, the ruling turned on the defendant's

"***admission*** to seven CGMP violations," which "suffice[d] to render the seized items adulterated." No. 19 C 3876, 2021 WL 2272402, at *3-4 (N.D. Ill. May 4, 2021) (emphasis added) (cited in Pls.' Br. at 10).

Here, there has been no admission of adulteration, no civil or criminal enforcement action against any of the Defendants, and no final regulatory action or determination by the FDA against any of the Defendants finding their API or VCDs adulterated. *See Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001) ("Claims of adulteration should be resolved by the FDA."). Rather, the record shows that from the time the medications were approved through the time of their recall, there was no specification for nitrosamine impurities in VCDs; the USP did not contain any standard relating to NDMA or NDEA in VCDs; there was no FDA standard, testing methodology, or other regulatory standard or requirement pertaining to limits of NDMA or NDEA in VCDs; the alleged presence of trace levels of purported nitrosamine impurities in Defendants' products did not alter their bioequivalence, clinical efficacy, or how they worked; and all at-issue API and VCDs met their compendial and approved Drug Master File and ANDA specifications. (*See* § I.C, *infra*; Defs.' SUMF ¶¶ 68, 72-73, 94, 98-101.)

In addition, the FDA expressly stated that "the presence of NDMA was unexpected and [was] thought to be related to changes in the way the active substance was manufactured." (Defs.' SUMF ¶ 61 (quoting Defs.' SUMF Ex. 1, July

13 FDA News Release at 1); *see also* Defs.' SUMF ¶¶ 64-65 (quoting Defs.' SUMF Ex. 65, Jan. 25 FDA Statement at 3).) Dr. Scott Gottlieb, the FDA Commissioner, explained that prior to the FDA's becoming aware of the presence of NDMA in ZHP's valsartan API, "neither regulators nor industry fully understood how NDMA could form during [ZHP's manufacturing] process," which is why "manufacturers would not have been testing for it." (*Id.* ¶¶ 62-63 (quoting Defs.' SUMF Ex. 64, Aug. 2018 Gottlieb Statement at 4).) Thus, even according to the FDA's statements, there is, at a minimum, a "factual issue" as to whether the VCDs were adulterated.[5]

Plaintiffs also argue that Defendants breached express warranties that the medications were "the FDA approved and USP compliant formulations of those products, as listed in the Orange Book," based on supposed "undisputed" evidence that the medications: (1) did not "match the approved formulation" for valsartan due to the presence of nitrosamine impurities; (2) were "not CGMP compliant"; (3) were "not in conformance with compendial standards; and (4) were all "contaminated

[5] Plaintiffs do not address this evidence of the FDA's own statements. Instead, they attack the testimony of Dr. Ali Afnan and other defense experts, who opine, *inter alia*, that "[n]ew[] information not available while a product was on the market cannot retroactively render a product adulterated." (Defs.' SUMF Ex. 12, Amended Rep. of Dr. Ali Afnan, Ph.D. ("Afnan Rep.") ¶ 210, Jan. 11, 2023.) Although the Court excluded some of Dr. Afnan's testimony, it did not exclude his testimony that, "to the best of [his] knowledge and experience, at the time of the FDA recall of VCDs in 2018, the FDA had not yet developed an adequate test for nitrosamines formed in ZHP's solvent extraction processes." (ECF 2581 at 6.) That testimony, of course, aligns with the FDA's public statements.

with genotoxic, probable human carcinogens NDMA or NDEA." (Pls.' Br. at 2-3, 8-25.) Even if the Court concludes that Plaintiffs have presented sufficient evidence to raise a material fact question as to one or more of these theories, at most, they present a factual dispute for the jury to decide.

1. The Record Confirms That Defendants' Products Matched The Approved Formulation For Valsartan.

Plaintiffs assert that the at-issue valsartan API and finished-dose VCDs "were not what they purported to be"—i.e., "FDA-approved 'valsartan'" identical to the branded version (i.e., Diovan and Exforge). (Pls.' Br. at 8-9.) However, approved generic drugs need not be identical to their RLD counterparts. Rather, for an ANDA holder to obtain approval for a generic drug, it must demonstrate to the FDA that its product is pharmaceutically equivalent and bioequivalent to the RLD. (Defs.' SUMF ¶ 88.) *See also* 21 C.F.R. § 314.94(a)(7); 21 U.S.C. § 355(j)(2)(A)(iii)-(iv). Pharmaceutical equivalence means, *inter alia*, that the approved generic drug is the same as the RLD in terms of active ingredient(s), strength, dosage form, and route of administration. (Defs.' SUMF ¶ 89.) *See also* 21 U.S.C. § 355(j)(2)(A)(iii). Bioequivalence means the generic product is absorbed into the bloodstream at a similar rate and similar extent as the RLD. (Defs.' SUMF ¶ 90; *see also* Defs.' SUMF Ex. 83, *Bioavailability and Bioequivalence: An FDA Regulatory Overview*, *Pharmaceutical Research*, Vol. 18, No. 12, December 2001.)

Plaintiffs are unable to show that Defendants' medications failed to satisfy either requirement because the presence of trace levels of impurities does not implicate pharmaceutical equivalence or bioequivalence. (Defs.' SUMF ¶ 92.) Indeed, the FDA allows different impurity profiles in drugs, and changes in impurities do not create different or new drugs. (*Id.* ¶ 93.) Moreover, Defendants identified evidence in their omnibus SUMF showing that the trace presence of NDMA in Defendants' valsartan API and generic finished-dose VCDs did not alter their bioequivalence or clinical efficacy; nor did it have any impact on how the VCDs work—i.e., their pharmacokinetics or pharmacodynamics. (*Id.* ¶ 94.)

For example, the Court ruled that defense expert Dr. Michael Bottorff may opine that the "contaminated VCDs function the same in the human body as uncontaminated VCDs." (ECF 2581 at 11.) Plaintiffs' expert, Dr. Najafi, testified that a generic drug can be bioequivalent to the branded version without having an impurity profile that matches that of the RLD. (Defs.' SUMF Ex. 73, Najafi 2022 Dep. 20:9-10, 20:23-21:4.) Moreover, the FDA's testing showed that "not all products made using ZHP valsartan API contain[ed] the NDEA impurity." (Defs.' SUMF ¶ 49 (quoting Defs.' SUMF Ex. 57, FDA News Release, Sept. 13, 2018).) This evidence reflects, at most, a disputed factual question as to whether the VCDs were therapeutic or generic equivalents, precluding summary judgment in Plaintiffs' favor.

In sum, Defendants' products were what they purported to be—approved versions of generic valsartan. Accordingly, either summary judgment should be granted in favor of Defendants on this issue or the question should be left to the jury to decide.

2. Defendants' Purported CGMP Violations Are, At Most, Disputed Questions Of Fact For The Jury.

Plaintiffs' contention that the "undisputed record" establishes that Defendants violated CGMPs (Pls.' Br. at 12-19) similarly ignores substantial evidence showing that Defendants fully complied with those standards.[6]

Plaintiffs argue that ZHP "independently violated CGMPs" by failing to test for the potential creation of nitrosamines in connection with the TEA with sodium nitrite quenching and zinc chloride manufacturing processes. (Pls.' Br. at 12-19.)[7]

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[6] Plaintiffs highlight statements from the Class Certification Opinion that Defendants "may be hard pressed to refute that their conduct resulted in nitrosamine contamination of VCDs," and that such "contamination resulted from defendants' non-compliance of CGMPs at some level." (*See* Pls.' Br. at 16 (quoting ECF 2261 at 21).) Although Defendants respectfully disagree with those statements, they were made in the context of a predominance finding under Rule 23 (without the benefit of liability-related evidence). As a result, "***they do not bind the fact-finder on the merits***." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 318 & n.19 (3d Cir. 2008) (emphasis added) (collecting cases); *accord Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305 (3d Cir. 2016) (predominance analysis "is not a merits determination"). Moreover, the Court did not make any findings of specific CGMP violations by specific Defendants, much less connect such violations to the API and VCDs at issue here.

[7] Plaintiffs falsely claim that ZHP employee Eric Gu admitted that "every batch" showed the "NDMA peak just after the Toluene peak on the chromatograms," yet

However, as the FDA has explained, "it needs to be recognized that the risk of an impurity can occur in order to know that it should be tested for." (Defs.' SUMF Ex. 64, Aug. 2018 Gottlieb Statement.) The applicable regulatory guidance standards similarly "limit[]" testing to issues "that might reasonably be expected based on knowledge of the chemical reactions and conditions involved." FDA Q3A § 3.1, https://www.fda.gov/media/71727/download (last accessed Jan. 20, 2024).[8] The FDA has already found that the presence of NDMA was "not anticipated," i.e., not foreseeable, based on the relevant scientific knowledge. (Defs.' SUMF Ex. 64, Aug. 2018 Gottlieb Statement.) Indeed, none of the FDA chemists who reviewed ANDA applications for valsartan products expressed any concerns over the two manufacturing processes in question. (Afnan Rep. ¶ 145 (Ex. 10 to Cert. of Jessica Davidson ("Davidson Cert.")).)

Importantly, Plaintiffs' two designated experts, Dr. Stephen Hecht and Dr. Ramin Najafi, did not identify any scientific literature reporting the potential

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failed to test for the presence of nitrosamines. (Pls.' Br. at 14 (quoting ZHP SUMF ¶ 71).) To the contrary, Mr. Gu explicitly stated in his deposition that he does not "know the truth about, you know, how often [the peaks] appear in the final product" when counsel pressed Mr. Gu on whether he knew that the "peak was there on every single batch." (ZHP SUMF Resp. ¶ 71 (quoting Dep. of Eric Gu 339:13-340:22, Apr. 6, 2021, ZHP SUMF Ex. 21).) In any event, as detailed in text, the NDMA peak reflected an ***unknown*** impurity prior to the 2018 recall, meaning that there was no regulatory requirement to test for it.

[8] *See also* ICH Q3A § 3.1, https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf (last accessed Jan. 20, 2024) (same).

formation of NDMA or NDEA impurities in valsartan API at the time it was manufactured during the relevant time period. Regarding NDEA, Dr. Najafi conceded that he did not even know it was possible for ZHP's manufacturing processes to create NDEA until he began work on this litigation. (*See* Defs.' SUMF Ex. 58, 1/18/23 Najafi Dep. 192:18-193:15.) And Dr. Hecht admitted that the nitrosation of a tertiary amine like TEA is extremely rare. (*See* Defs.' SUMF Ex. 59, 7/6/21 Hecht Rep. at 18, 20.) Drs. Hecht and Najafi rely on a single Australian textbook for the proposition that ZHP should have realized that DMF could decompose into DMA (leading to the formation of small amounts of NDMA), but that sole reference only addressed DMF at its boiling point, and both conceded that ZHP's manufacturing processes never reached the temperature necessary for DMF to boil. (Defs.' SUMF Ex. 58, 1/18/23 Najafi Dep. 206:11-19; *see also* Defs.' SUMF Ex. 61, Hecht Dep. 218:7-15.) Finally, although Dr. Najafi asserts that a 2017 email from ZHP employee Jinsheng Lin shows that ZHP did have knowledge of the potential for NDMA or NDEA to result from its manufacturing processes (*see* Defs.' SUMF Ex. 60, 2022 Najafi Rep. at 30-31), that email is not about Valsartan API; it is susceptible to varying interpretations; and it cannot make up for ample contrary evidence belying the notion that ZHP had any reason to know of the potential for

nitrosamine formation, as elaborated in ZHP's opposition to Plaintiffs' ZHP-specific motion for partial summary judgment.[9]

As to Teva, each of Plaintiffs' asserted CGMP violations is based on incomplete, erroneous or false assertions from their Teva-specific statement of facts. (*See* Pls.' Br. at 16-18.) The record refutes each of Plaintiffs' claimed CGMP violations with respect to Teva, showing that:

- Actavis followed its own change control procedures relating to analysis and approval of ZHP's manufacturing process change for valsartan API, including performing a complete risk assessment based on the process change for ZHP's valsartan API. (Teva's Resp. to Pls.' Statement of Material Facts as to Teva ("Teva SUMF Resp.") ¶ 42.)

- Teva performed complete specification testing for all valsartan API sourced from ZHP both before and after the process change and confirmed that every batch of API received from ZHP met all applicable specifications. (*Id.* ¶¶ 48, 51-55, 62-63.)

- Teva properly described ZHP's process change in its communications with the FDA. (*Id.* ¶¶ 56-59.)

- Teva never purchased ZHP's API made through the TEA process. (*Id.* ¶ 78.)

[9] The draft 2008 FDA Guidance titled "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches" (*see* Pls.' Br. at 13 (citing ZHP SUMF ¶¶ 57-58)), does not support Plaintiffs' argument for multiple reasons. ***First***, as noted in the document itself, the guidance was "being distributed for comment purposes only" and "Not for Implementation." FDA, Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products (Dec. 2008) at 1, 2 (Davidson Cert. Ex. 8). ***Second***, the draft guidance recognizes that while "every feasible technical effort should be made to prevent the formation of genotoxic or carcinogenic compounds . . . completely preventing the formation of or removing an impurity of concern may not be possible in many cases." *Id.* at 7. (*See also* Dep. of Eric Gu 71:1-18, Apr. 5, 2021, ZHP SUMF Ex. 31.)

- The finding of nitrosamines in ZHP's API was, even according to the FDA, unexpected and not anticipated. (*Id.* ¶ 60.)

- Plaintiffs' expert, Dr. Hecht, admits that Teva and the other Defendants would not have identified NDMA in the chromatograms unless they were specifically looking for it, because the peaks would be too small. (*Id.*) Dr. Hecht further acknowledged that there is no evidence Teva was aware of the potential for nitrosamine formation in valsartan API prior to June 2018. (*Id.*)

- Prior to July 2018, there was no FDA standard, testing methodology, or regulatory standard relating to NDMA in VCDs. (*Id.*)

- Teva's expert, Timothy Anderson, specifically testified to Actavis's pre-acquisition SOPs governing change controls, risk assessments, and quality oversight of API suppliers. (*Id.* ¶ 79.)

- Prior to Actavis's acquisition by Teva in August 2016, Teva independently audited ZHP's facility that supplied valsartan API to Actavis during the entire time period the at-issue valsartan API was being manufactured. (*Id.* ¶ 64.)

- Teva consistently audited ZHP's facilities, did not make any critical-level observations during any audit of ZHP, and there is no evidence it failed to request information or to follow up as necessary regarding observations made during its audits. (*Id.* ¶¶ 65-72, 80-81.) Teva's findings mirror the FDA's. (Defs.' SUMF ¶ 16.)

- Teva properly communicated its findings related to nitrosamine impurities to the FDA and its Field Alert was timely according to Teva's own standard operating procedures. (Teva SUMF Resp. ¶¶ 73-76.)

- There is no evidence of the existence of any literature and guidance prior to the actual detection of NDMA in valsartan indicating that the valsartan API manufacturing process used by ZHP could form nitrosamines. Nor is there any evidence that Teva or Actavis failed to find or ignored literature and guidance about evaluating valsartan API or any other API for genotoxic impurities. (*Id.* ¶¶ 109-122.)

- Plaintiffs mischaracterize the evidence regarding Teva's audit finding with respect to the presence of the NDMA impurity in ZHP's API, and the evidence is in all events irrelevant as it pertains to post-detection and post-recall events after Teva had already put a hold on its finished-dose VCDs and withdrawn them from the market, and thus could not have been causally related to Plaintiffs' alleged damages. (*Id*. ¶¶ 82-96.)

- Teva's supposed release of VCDs containing non-ZHP valsartan API into the market has nothing to do with the at-issue VCDs and is therefore irrelevant to Plaintiffs' claims. (*Id*. ¶ 77.)

With respect to Torrent, Plaintiffs' alleged CGMP violations rely on incomplete, misleading, or false assertions from their Torrent-specific statement of facts. (*See* Pls.' Br. at 18-19.) In particular, Plaintiffs make the sweeping conclusion that Torrent's facility was non-compliant with CGMP on the grounds that an Establishment Inspection Report ("EIR") contained observations regarding lab controls and test procedures. (*See id.* at 18.) While an EIR does not constitute a final resolution or finding from the FDA, Plaintiffs ignore the fact that in the years leading up to the recall, Torrent passed numerous FDA inspections, including one in April 2017. (Defs.' SUMF ¶ 25.) Plaintiffs also assert that Torrent did not do enough to control for genotoxic impurities. (*See* Pls.' Br. at 18-19.) This characterization ignores undisputed facts in the record that Torrent was routinely testing all API received from ZHP, and disregards the factual record regarding the ability to test for NDMA and NDEA during this time. (*See* Defs.' SUMF ¶¶ 26, 31; *see also* Torrent's Response to Plaintiffs' Statement of Material Facts as to Torrent ("Torrent SUMF

Resp.") ¶¶ 9-12, 20.) For the remainder of Plaintiffs' claims, they rely on the mischaracterization of the deposition testimony of a single witness. (*See* Pls.' Br. at 18.) This approach falls woefully short of establishing that Torrent did not comply with CGMPs as a matter of law.

3. The Record Confirms That Defendants Did Not Violate Compendial Standards.

Plaintiffs also argue that the Court should find that Defendants' VCDs were adulterated for "[n]ot [c]omplying with [c]ompendial [s]tandards," because USP specifications "did not permit NDMA or NDEA impurities in valsartan API," and the Orange Book "did not refer to" NDMA or NDEA impurities. (Pls.' Br. at 19-22.) Neither argument has any merit.

With respect to USP specifications, Plaintiffs are conflating the lack of any specific limit for NDMA and NDEA in the USP monograph for valsartan API with a prohibition on its presence. Indeed, Plaintiffs expressly acknowledge that "NDMA and NDEA ***are not listed as valsartan impurities*** in the USP monograph." (Pls.' Br. at 23 (emphasis added); *see also* Dep. of Susan Bain 211:25-212:3, Jan. 31, 2023 (Davidson Cert. Ex. 18) (Plaintiffs' expert unable to identify any USP monograph mentioning nitrosamine impurities); Teva SUMF Resp. ¶ 41 (Plaintiffs' expert Philip Russ admits he reviewed relevant Teva materials and saw no issues with Teva's compliance with the VCDs' compendial specifications).) At all relevant times, including in 2012—when ZHP submitted Amendment-002 to Drug Master

File No. 023491 changing its manufacturing process—the USP standards only provided explicit tests for, and limits regarding, three specific compounds for Valsartan: USP Valsartan Related Compound A (C24H29N5O3) ("Impurity A"); USP Valsartan Related Compound B (C23H27N5O3) ("Impurity B"); and USP Valsartan Related Compound C (C31H35 N5O) ("Impurity C"). (Defs.' SUMF ¶ 118; *see also* Defs.' SUMF ¶¶ 68, 72-73 (USP had no NDMA or NDEA standard during the relevant time period).) In truth, the FDA did not publish a table of interim acceptable intake limits for nitrosamines, including NDMA and NDEA, in VCDs until December 19, 2018, and did not confirm those limits until February 2021. (*Id.* ¶ 75 (citing Defs.' SUMF Ex. 69, FDA Recall Press Release at 13).) And even today, the USP does not prohibit the presence of trace amounts of nitrosamines; rather, it prescribes certain limitations that mirror those announced by the FDA. (*See id.* ¶ 76.)

Moreover, Plaintiffs have no evidence that the trace amounts of NDMA detected in the medications exceeded the FDA's imposed thresholds for either unknown or known impurities. To the contrary, Plaintiffs' expert, Philip Russ, admits that the highest level of NDMA detected in any ZHP API lots sold to Teva is approximately four times lower than the compendial identification threshold for unknown impurities. (Teva SUMF Resp. ¶ 8.) Moreover, even as to the three impurities that were expressly identified in the monograph, the USP prescribed a .1% threshold for variance with branded valsartan, a limit Plaintiffs are unable to

show the VCDs ever exceeded. (USP 35, Official Monographs (2012) at 5.60.10 (Davidson Cert. Ex. 19).) Thus, as Defendants' experts explain, at all relevant times prior to the recalls, Defendants' VCDs met the applicable USP standard. (Defs.' SUMF ¶ 86.)

Plaintiffs also argue that Defendants breached express warranties in that the VCDs "were not therapeutic or generic equivalents as set forth in the Orange Book." (Pls.' Br. at 21.) Putting aside that the Court has excluded Dr. Panagos's warranty opinions on this subject, the Orange Book does not contain any impurity information, let alone purport to prohibit the presence of any supposed impurities. *See* https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last accessed Jan. 20, 2024) (search criterion "Valsartan" under "Search by Proprietary Name, Active Ingredient or Application Number"). Nor have Plaintiffs presented any evidence that Diovan (the purportedly identical branded VCD) is devoid of nitrosamines. As the FDA has recognized, "nitrosamines are common in water," raising the possibility that processes like Novartis's that use water may contain nitrosamines, which may explain Valisure's testing results suggesting the presence of such alleged impurities in branded valsartan. (*See* ZHP SUMF Resp. ¶ 10.) In any event, as previously discussed, the trace presence of nitrosamines in generic VCDs did not alter their clinical safety; nor did it have any impact on their pharmacokinetics or pharmacodynamics. (*See* Defs.' SUMF ¶ 94.)

Plaintiffs also argue that Defendants did not comply with compendial standards because they did not undertake a "sound scientific appraisal" when ZHP changed the manufacturing process for its valsartan API. (Pls.' Br. at 19-20.) But this is just a repackaged version of Plaintiffs' CGMP theory (i.e., that Defendants failed to test for potential nitrosamine formation), which is illogical given the FDA's pronouncements regarding the state of scientific knowledge prior to 2018, as previously discussed. (Defs.' SUMF ¶¶ 62-65.) In any event, Defendants have presented extensive evidence of a full and proper appraisal of ZHP's process changes for valsartan API, including a complete risk assessment and specification testing both before and after the process changes. (*See id.*; ZHP SUMF Resp. ¶¶ 58, 60-62, 78; Teva SUMF Resp. ¶¶ 42, 48, 51-55, 62-63.)[10] Accordingly, even assuming that Plaintiffs had identified any express promises to their assignors and the subclass members regarding compendial requirements, their motion, at most, presents a disputed factual question as to Defendants' compliance with those standards.

[10] There is no truth to Plaintiffs' claim that "ZHP's risk assessment was limited to evaluation of the newly added solvent DMF." (Pls.' Br. at 14.) As ZHP communicated to the FDA, prior to adopting the Zinc Chloride process, ZHP conducted a detailed self-evaluation and assessment that included: "(1) Process changes content evaluation; (2) Suitability of specifications and analytical methods of intermediates and final substance evaluation; (3) Manufacturing equipment evaluation; (4) Assessment via lab-scale process research and development studies; (5) Quality risk assessment." (ZHP SUMF Resp. ¶ 78 (quoting ZHP02579954, at 962-65) (Davidson Cert. Ex. 9).)

Plaintiffs' authorities do not change this analysis. *Mylan Laboratories Ltd. v. United States Food & Drug Administration* concerned "a dispute about the right to 180-day marketing exclusivity" of Ranbaxy, which filed the first ANDA giving rise to such a right with respect to valsartan. 910 F. Supp. 2d 299, 301 (D.D.C. 2012). It did not address USP specifications or Orange Book requirements, much less suggest that the presence of trace amounts of nitrosamines prior to 2018 would render generic valsartan adulterated. And in *United States v. Lanpar Co.*, the court granted the government's motion for a preliminary injunction enjoining the sale and marketing of drugs after the defendant had pled guilty to two counts of shipping "adulterated" drugs throughout the United States. 293 F. Supp. 147, 149, 154-55 (N.D. Tex. 1968). Although the court noted that the "strength" and "quality" of the drug fell "below the standard established for it in the U.S.P." (rendering it adulterated), not even Plaintiffs claim that the VCDs here failed to satisfy "established" USP requirements on these key attributes. In short, Plaintiffs' cases further highlight the fact-intensive nature of their arguments.

4. <u>Defendants' Products Were Not "Contaminated" With A "Genotoxic" Or "Carcinogenic" Impurity.</u>

Plaintiffs' final theory of breach is that Defendants' products breached an "express warranty" that their drugs were not "contaminated," because all of their API and VCDs were "contaminated with genotoxic, probable human carcinogens NDMA or NDEA." (Pls.' Br. at 22-26.) However, whether NDMA or NDEA is

"genotoxic" or "carcinogenic"—and in particular whether either is "genotoxic" or "carcinogenic" at the level detected in Defendants' products—are among the most heavily contested issues in this litigation. Although the Court previously found that Plaintiffs' experts' general causation opinions were admissible, another court more recently reached the opposite conclusion on the same issue in a 341-page order, excluding as unreliable general causation opinions that are indistinguishable from those presented here, based on the same sources and methods—and in one instance, even the same expert. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075 (S.D. Fla. 2022).

In any event, far from endorsing Plaintiffs' theory of genotoxicity or carcinogenicity as a matter of law, this Court merely ruled that most of the competing evidence on causation would be admissible at trial (*see* ECF 1958, 1959, 1974), including defense experts' opinions that refute Plaintiffs' claims (*see* Teva SUMF Resp. ¶¶ 23, 97-99, 115, 119-20). Notably, Plaintiffs did not even move to exclude the opinions of Dr. Lewis A. Chodosh, who opines that "exposure to NDMA and/or NDEA in valsartan, at the doses to which [individuals] were potentially exposed, and for the durations to which [they] were potentially exposed, does not cause cancer in human beings." (Rep. of Lewis A. Chodosh, M.D., Ph.D. ¶ 179, Aug. 2, 2021 (Davidson Cert. Ex. 20).) Nor did Plaintiffs move to exclude the opinions of Dr. Herman Gibb, who concluded that there is no epidemiological evidence of a causal

connection between NDMA in valsartan and an increased risk of cancer. (Rep. of Herman J. Gibb, Ph.D., M.P.H. at 10, Aug. 2, 2021 (Davidson Cert. Ex. 21); Teva SUMF Resp. ¶ 120.)

The opinions of Defendants' other experts further explain that NDMA and NDEA are not genotoxic or carcinogenic at the trace levels detected in Defendants' products, that Plaintiffs' methodologies are unreliable because they ignore the fact that the exposure level is so small that any DNA damage that might occur would be fully repaired, and that potential genotoxic or carcinogenic impurities are unlikely to be identified or quantified at such low levels below the identification threshold. (*See* Teva SUMF Resp. ¶¶ 23, 97-99, 115, 119-20.) Defendants' evidence also shows that, although several organizations have classified NDMA and NDEA as "probable human carcinogens," that classification is based on animal studies; NDMA and NDEA are not known human carcinogens at any level; and there is no human cancer that has been demonstrated to result from exposure to NDMA or NDEA. (Teva SUMF Resp. ¶¶ 96, 100, 119-20.)

Plaintiffs also ignore the FDA's public statements on this subject, which further highlight the highly disputed nature of their safety theory. In particular, even with respect to the voluntarily recalled VCDs, the FDA advised patients to "continue taking their medicine until they have a replacement product." (Defs.' SUMF ¶ 81 (quoting Defs.' SUMF Ex. 1, July 13 FDA News Release at 1).) The FDA stated that

continuing to take the recalled VCDs was a "low risk" versus abruptly discontinuing their use, and estimated that if 8,000 people took the highest valsartan dose from NDMA-affected medicines daily for four years, there ***theoretically*** "may be one additional case of cancer over the lifetimes of these 8,000 people beyond the average cancer rate among Americans." (*Id.* ¶¶ 78, 82.) The FDA also described the levels of NDMA detected in ZHP's API as "trace amounts." (*Id.* ¶ 77.) These statements all directly refute Plaintiffs' attempts to characterize the TPP Trial Defendants' products as genotoxic and carcinogenic.

Finally, contrary to Plaintiffs' argument, the Court has ***not*** "already ruled that the presence of these genotoxins breached Defendants' warranties." (Pls.' Br. at 25-26 (citing ECF 775).) As previously discussed, the Court's ruling at the dismissal stage was not a decision on the merits; rather, it merely afforded Plaintiffs an opportunity to offer evidence in support of their claims—e.g., that Defendants' medications were the "chemical equivalent of the Orange Book pharmaceutical." (*Id.* at 14 (citation omitted).) Discovery has now shown that Plaintiffs cannot withstand Defendants' Motion for Summary Judgment, much less prevail on their express warranty claims as a matter of law prior to trial.

In short, in the event the Court denies Defendants' Motion for Summary Judgment, it should, at a minimum, permit a jury to decide Plaintiffs' theories of breach of warranty.

II. PLAINTIFFS ARE NOT ENTITLED TO PARTIAL SUMMARY JUDGMENT ON THEIR CLAIMS FOR VIOLATION OF CONSUMER PROTECTION STATUTES.

A. Plaintiffs' Request For Partial Summary Judgment Is Improper Because It Ignores Multiple Liability Elements.

Plaintiffs' argument that they are entitled to partial summary judgment on the consumer protection claims in Subclass A fails for similar reasons. (Pls.' Br. at 26.) In so arguing, Plaintiffs purport to address the following three elements of their claims: (1) that the defendant engaged in conduct proscribed by the relevant act; (2) that the conduct occurred in trade or commerce; and (3) that the plaintiff suffered injury and damages.[11] (*Id.*) As elaborated in Defendants' Motion for Summary Judgment, Plaintiffs have no evidence capable of proving either the first or third elements—i.e., that Defendants engaged in any false or misleading statements or

[11] As explained in Defendants' motion for summary judgment (Defs.' Br. at 7-8), this Court previously held that Plaintiffs' claims are governed by "the law[s] of [their] home state[s]"—i.e., where each TPP is located (ECF 818 at 10). Yet, each of the TPP subclass definitions is limited to specific states in which TPP subclass members "paid any amount of money" for VCDs, which may or may not be their home states. (ECF 2532-6.) This disconnect between the state whose law governs (i.e., the TPP's home state) and the states encompassed by the subclass definitions (i.e., the state where each TPP paid for valsartan) makes it impossible to discern what law governs each unnamed subclass member's claims. The mismatch between the defined subclasses and the Court's prior choice-of-law ruling makes it impossible and impractical for the TPP Trial to proceed. For present purposes, however, this opposition assumes without conceding (and contrary to the law of the case) that the claims at issue are governed by the 43 jurisdictions identified across the four subclasses.

concealment or that they incurred any cognizable injury. (*See* Defs.' Br. at 18-20, 22-31.) Thus, Defendants are entitled to summary judgment, not Plaintiffs.

Even if Plaintiffs could establish a material dispute as to any of these elements, their request for partial summary judgment suffers from the same defect that dooms their warranty arguments: it would not resolve the claims in their entirety. This is so because Plaintiffs ignore the requirements of causation/reliance, as well as independent procedural hurdles that preclude commercial entities from suing under consumer protection laws or foreclose consumer protection class actions altogether. (*See* Defs.' Br. at 22-23.) And although Plaintiffs argue in a single conclusory sentence that "intent" is "not required" under any of the relevant state laws (Pls.' Br. at 36), the relevant states ***do*** require "evidence that Defendants knew or should have known about the" alleged falsity or unfairness. *See, e.g.*, *Smith v. Kershentsef*, 636 F. Supp. 3d 533, 537 (E.D. Pa. 2022) ("[p]laintiff cannot meet his summary judgment burden for his UTPCPL claims" because he "has presented no evidence" of the deception element); *Mehovic v. Ken Wilson Ford, Inc.*, 439 S.E.2d 184, 185 (N.C. Ct. App. 1994) (imposing similar requirement for "unfair or deceptive acts or practices within the meaning of N.C. Gen. Stat. § 75-1.1"). And as Plaintiffs expressly acknowledge, the parties "dispute" whether Defendants knew of the potential for nitrosamine formation in their VCDs during the relevant time period

(Pls.' Br. at 34), meaning that a jury would have to decide that fundamental question after trial.

In short, resolving Plaintiffs' consumer protection arguments on the merits would fail to "materially advance the litigation in any way," *In re G-I Holdings, Inc.*, 2007 WL 1412294, at *4; for this reason alone, the Court should deny Plaintiffs' request for partial summary judgement on these claims.

B. Plaintiffs Have Not Proven Any "Deceptive" Or "Unfair" Conduct.

Plaintiffs' argument that Defendants engaged in "deceptive" and "unfair" conduct is based almost entirely on a single Third Circuit case, *Federal Trade Commission v. Wyndham Worldwide Corp.*, 799 F.3d 236 (3d Cir. 2015), and FTC policy statements that *Wyndham* considered in the context of interpreting the FTC Act alone and applying that federal statute to companies with allegedly deficient cybersecurity. (Pls.' Br. at 27-28.) Plaintiffs assert that 11 of the 18 states whose laws are at issue "explicitly . . . incorporate" federal law under the FTC Act. (*Id.* at 27.) That is simply not true. The states Plaintiffs identify generally look to FTC decisional law for guidance (with varying levels of deference), or merely note that their laws were modeled on the FTC Act; they have not adopted wholesale the law of the FTC Act.[12] Plaintiffs do not even articulate what standard applies under

[12] *See, e.g., Cheramie Servs., Inc. v. Shell Deepwater Prod., Inc.*, 35 So. 3d 1053,

Missouri, Nebraska, Oklahoma, Oregon or Pennsylvania law; instead, they make only a conclusory argument that "the very same result is reached." (*Id.* at 30, 34-35.) And Plaintiffs also fail to address the governing standard under both Illinois law and North Dakota law. (*See id.* at 35 n.18, 37 n.22.)

"Although every state's consumer protection statute prohibits deceptive acts, they do not utilize a uniform definition of deception." *In re McCormick & Co.*, 422 F. Supp. 3d 194, 228 (D.D.C. 2019). For example, in Connecticut, the false or misleading statement must be "'likely to affect consumer decisions or conduct.'" *Id.* (quoting Conn. Judicial Branch Civil Jury Instr. 5.2-7). By contrast, "in New Hampshire, a '"deceptive" act or practice is simply one that has the capacity to deceive.'" *Id.* (quoting *Fowler v. O'Hara*, No. 2182015CV01109, 2016 WL 9137116 (N.H. Super. Ct. Dec. 22, 2016) (jury instruction)). The states also "apply different tests when determining what qualifies as unfair conduct prohibited by a particular consumer protection statute," and the differences "are significant." *In re*

1056 & n.4 (La. 2010) (indicating that Louisiana law was "modeled after" the FTC Act, not that it is interpreted the same); *FTC v. Crescent Publ'g Grp., Inc.*, 129 F. Supp. 2d 311, 318 (S.D.N.Y. 2001) (New York law "is modeled in part on the FTCA"); Haw. Rev. Stat. Ann. § 480-2 (providing for "due consideration" of FTC Act law); *Borgen v. A & M Motors, Inc.*, 273 P.3d 575, 583 (Alaska 2012) (stating generally that "due consideration and great weight" are afforded to FTC Act interpretations) (citation omitted); Fla. Stat. Ann. § 501.204 (same); Conn. Gen. Stat. Ann. § 42-110b (declaring an intention that state commissioner "shall be guided" by FTC Act interpretations, not that courts must follow those interpretations); *Johnson v. Phoenix Mut. Life Ins. Co.*, 266 S.E.2d 610, 620 (N.C. 1980) (looking to federal law for "guidance" rather than requiring fidelity to federal law).

EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., MDL No. 2785, 2020 WL 1180550, at *54-55 (D. Kan. Feb. 27, 2020). For example, Connecticut, Florida, Hawaii, Illinois, Missouri, and Oklahoma apply a three-factor test that is materially different from the FTC test; by contrast, Nebraska and New Hampshire have their own distinct tests, with the latter state requiring a determination that "the objectionable conduct must attain a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce." *Axenics, Inc. v. Turner Constr. Co.*, 62 A.3d 754, 769 (N.H. 2013) (citation omitted). And by even further contrast, California employs multiple different tests. *In re EpiPen*, 2020 WL 1180550, at *55 & nn.61, 63, 65.[13] In short, Plaintiffs have not come close to establishing that they are entitled to judgment as a matter of law against this checkerboard of disparate legal standards for deception and unfairness.

Even if the laws of all of the Subclass A states were the same and aligned fully with the FTC, Plaintiffs' motion would still fail because the record lacks any evidence, much less undisputed evidence, to support the essential element of "deceptive" or "unfair" conduct under any standard.

[13] Although Plaintiffs insist that New Hampshire "explicitly . . . incorporate[s]" FTC Act law and guidance (*see* Pls.' Br. at 27), the statute merely ***permits*** (but does not require) courts to look to the FTCA Act for "guid[ance]." N.H. Rev. Stat. § 358-A:13 ("[T]he courts ***may*** be guided . . . .") (emphasis added).

1. Plaintiffs Have Not Established Any "Deceptive" Conduct.

"Deceptive" conduct, at a minimum, requires evidence of a false or deceptive statement or omission. *See In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 113 F.3d 1484, 1498 (8th Cir. 1997) ("Without evidence of a false representation, the misrepresentation claim cannot succeed . . . ."). Thus, in a case where a plaintiff is alleging that purported statements regarding compliance with regulatory standards were deceptive, he or she has the burden to "demonstrate, through expert testimony or otherwise, that" the product was not tested or otherwise produced in accordance with those standards. *See FTC v. Innovative Designs, Inc.*, No. 20-3379, 2021 WL 3086188, at *4 (3d Cir. July 22, 2021) (affirming grant of judgment against FTC on falsity theory where the FTC's key expert's testimony had been properly stricken and FTC had failed to show that the product at issue was not tested in a manner consistent with industry standards).

Here, Plaintiffs' deception claim is based on the theory that "Defendants made ***false written representations*** that their VCD products" were "FDA-approved, generic" VCDs and "met the compendial standards and were the therapeutic equivalent of the brand name drugs." (Pls.' Br. at 29.) That is identical to the theory Plaintiffs are advancing in support of their express warranty claims and cannot be resolved in Plaintiffs' favor prior to trial for all the reasons previously discussed—i.e., Defendants' products were what Defendants represented them to be (valsartan),

ZHP's valsartan API and Defendants' VCDs were therapeutically equivalent and bioequivalent to their approved RLDs, met all approved Drug Master File, ANDA, and compendial specifications, and did not exceed reporting thresholds for unknown impurities. *See* § I.C, *supra*.[14]

In addition, even though Plaintiffs expressly recognize that, "[t]o establish deception . . . the representation must be material" (Pls.' Br. at 28), they do not explain how they could prove this requirement at trial, let alone what undisputed evidence supposedly entitles them to summary judgment. Despite the variations among the relevant state laws, they generally either apply an objective or subjective test—neither of which can be met in this case. *See, e.g.*, *State ex rel. Shikada v. Bristol-Myers Squibb Co.*, 526 P.3d 395, 418 (Haw. 2023) (applying objective "reasonable consumer" test and reversing summary judgment ruling); *Mack v. Plaza Dewitt Ltd. P'ship*, 484 N.E.2d 900, 906 (Ill. App. Ct. 1985) (applying subjective test based on how the plaintiff would have acted). Objectively, it is undisputed that

[14] Plaintiffs suggest that they need only show "sales of hazardous" products "without adequate disclosures" or "failure to meet warranty obligations." (Pls.' Br. at 28 (quoting Oct. 14, 1983 *FTC Policy Statement on Deception*, ZHP SUMF Ex. 124.) However, Plaintiffs have not even attempted to show that the relevant states have incorporated such a standard into their consumer protection statutes. And even if they had, Defendants did not make any express (much less inadequate) disclosures or warranties. *See* § I, *supra*. Plaintiffs' argument is also illogical because the *FTC Policy Statement on Deception* confirms that whether a particular statement or omission is misleading is a question of fact that depends on the "nature and extent" of claims made. (ZHP SUMF Ex. 124.)

there were no regulations or limits applicable to NDMA or NDEA content during the relevant time period. (Defs.' SUMF ¶¶ 68, 72, 73.) Nor is there any dispute that the FDA told patients to continue taking VCDs containing NDMA or NDEA. (*Id.* ¶ 78.) And the only evidence in the record with regard to subjective materiality is the fact that neither Emblem nor SummaCare relied on any alleged misrepresentations, which means that the purportedly misrepresented information could ***not*** have been of any importance to them. (*Id.* ¶¶ 123-124.) Accordingly, Plaintiffs have fallen well short of their burden of establishing a deceptive trade practice.

2. Plaintiffs Have Not Established Any "Unfair" Conduct.

Plaintiffs argue that Defendants engaged in "unfair" conduct under the three-factor unfairness test set forth in the 1980 FTC Policy Statement on Unfairness. (*See* Pls.' Br. at 31.) That test looks to: (1) the substantiality of the injury; (2) whether it was outweighed by any countervailing benefits; and (3) whether consumers could have reasonably avoided the injury. *See Wyndham*, 799 F.3d at 243. Plaintiffs have made no showing that the FTC unfairness standard, as described in *Wyndham*, has been adopted by any State Consumer Protection Laws Subclass A states. Even if they had, the Court should find that Plaintiffs have no evidence that could satisfy that test or, at minimum, permit the jury to decide that question after trial.

The closest Plaintiffs come to addressing substantiality of injury is their conclusory assertion that the "sale into the stream of commerce" of Defendants' VCDs caused "substantial injury" to someone. (Pls.' Br. at 32-33.) However, as elaborated both in Defendants' Motion for Summary Judgment and *supra*, Plaintiffs received exactly what they paid for: effective blood pressure medication for their members. *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *9 (D.N.J. July 10, 2009). (*See also* Defs.' SUMF ¶ 79-80 (acknowledgements by Plaintiffs and their experts that the VCDs were effective to treat hypertension).) Moreover, the FDA concluded that any risk from the at-issue VCDs was "very small," which is a far cry from a "substantial injury." (Defs.' SUMF ¶ 78; *see generally* Defs.' Br. at 24-28.)[15]

Even assuming Plaintiffs' theory of "injury" had any legal or factual support, any such "injury" was outweighed by the countervailing benefits of the availability of Defendants' VCDs. Those medications indisputably provided effective, life-saving hypertension treatment. (Defs.' SUMF ¶¶ 79-80.) The FDA expressly recognized that those benefits outweighed the risk of limited NDMA/NDEA exposure when it instructed patients to continue taking VCDs subject to the recall until an appropriate replacement was prescribed. (*Id.* ¶ 78.) Plaintiffs do not contest

[15] Plaintiffs also do not argue that they have suffered any injury from, for example, purchasing replacement medication. (*See* Defs.' Br. at 28-31.)

those facts, but only assert that the VCDs were "economically worthless" based on this Court's ruling at the dismissal stage—when it accepted all of Plaintiffs' allegations as true—and a collection of cases that accepted a full-refund damages methodology as a viable class-wide damages model at the Rule 23 class certification stage. (*See* Pls.' Br. at 33 & n.17.) At this stage of the proceedings, however, the Court must determine whether it is legally viable to treat effective medication as categorically worthless based on an expert's *ipse dixit*. And as the applicable caselaw makes clear, such a theory is not even capable of withstanding Defendants' Motion for Summary Judgment, much less warranting the extraordinary step of deciding this element in Plaintiffs' favor before trial. *See Am. Fed'n of State Cnty. & Mun. Emps., Dist. Council 47 Health & Welfare Fund v. Ortho-McNeil-Janssen Pharms., Inc.*, 857 F. Supp. 2d 510, 515 (E.D. Pa. 2012) (granting defendants summary judgment and rejecting "worthless" theory of injury "[b]ecause there [was] no evidence that any [recalled] patches for which [TPPs] paid were not used as intended"). (*See also* Defs.' Br. at 24-28.)

Finally, Plaintiffs half-heartedly claim that it is "undisputed" that Plaintiffs "could not have reasonably avoided" their so-called injury because "there was no way for them to know that" the VCDs they paid for contained trace amounts of nitrosamines. (Pls.' Br. at 33.) This theory—which Plaintiffs do not even try to support with any record evidence—is belied by the testimony from Emblem's

representative, who did not notice any change to any Emblem formulary even after the valsartan recall. (Defs.' SUMF ¶ 124.) Accordingly, Plaintiffs have not satisfied any of the three factors they claim control the unfairness inquiry, much less carried their burden of establishing—as a matter of law—that Defendants engaged in such purported misconduct before trial.

In short, in the event the Court denies Defendants' Motion for Summary Judgment, it should, at a minimum, permit a jury to decide Plaintiffs' theories of deceptive and unfair conduct.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for partial summary judgment in its entirety.

Dated: January 22, 2024 Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 22, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson
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